The Examiner states that the word "clsass" was misspelled and that appropriate correction was required. The specification has been amended to correct the typographical error.

The Examiner has objected to Claim 6 under 37 C.F.R. 1.75(c) as being in improper form. Claim 6 has been amended to place the claim in proper multiple dependent form.

The Examiner has rejected Claims 20 to 23 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention without undue experimentation. Applicants respectfully traverse this rejection. The Examiner has stated that the scope of Claim 21 is not commensurate with the enablement provided by the disclosure with regard to the concept of "modulating an immune response." The Examiner contends that the *in vitro* experiments conducted by Applicants are of little relevance to *in vivo* modulation of the immune system.

In this regard, Applicants respectfully point out that the references cited by the Examiner are inapposite because they relate to limitations of certain cell lines and immune assays in applications where the overall effects observed are not always the same as those which occur *in vivo* and where the molecular mechanisms may not reflect what happens *in vivo*. To the contrary, Applicant's *in vitro* testing precisely mimics the mechanisms occurring *in vivo*. It is widely accepted that for any form of vaccine comprising a non-repetitive polypeptide vaccine, including T-cell dependent, the presentation of immunogenic peptides by MHC molecules is required to produce an effect *in vivo*. Examples 1 and 2 demonstrate the presentation of these immunogenic peptides by MHC molecules *in vitro*. This presentation is a necessary prerequisite for modulating the immune system response and therefore, provides a simple and acceptable correlation between the *in vitro* examples and what occurs *in vivo*.

This being the case, 35 U.S.C. § 112, first paragraph does not form a proper basis for rejecting Claims 20 to 23. Accordingly, Applicants respectfully request

that the rejection of Claim 20 to 23 under 35 U.S.C. § 112, first paragraph, be withdrawn.

On the merits, the Examiner has rejected Claims 1, 5 to 11, 13 and 20 to 23 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,283,323. The Examiner states that the '323 patent teaches a chimeric polypeptide comprising an immnoglobulin molecule, which comprises a binding portion, and a translocation portion and an effector portion. Applicants respectfully traverse this rejection.

Although Applicants disagree with the Examiner, Applicants have amended Claim 1 to expedite prosecution. Support for the amendment can be found in Claim 13 and generally throughout the specification and figures. For a proper 35 U.S.C. § 102(b) rejection, every element in a claim must be taught by the reference. Applicants respectfully point out that the '323 patent does not teach or suggest a translocation portion. As amended, Claim 1 and Claims 5 to 11, 13 and 20 to 23, depending from Claim 1, require a translocation portion.

Therefore, 35 U.S.C. § 102(b) does not provide a proper basis for rejection and, accordingly, Applicants respectfully request that the rejection of Claims 1, 5 to 11, 13 and 20 to 23 based on 35 U.S.C. § 102(b) be withdrawn.

The Examiner has rejected Claims 1 to 3 and 5 to 23 under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,283,323 in view of Fawell et al (1994), Baier et al. (1995), and Noguchi et al (1994). Applicants respectfully traverse this rejection.

At the outset, please note that Baier et al was published in April of 1995, after the application's priority dates, and therefore, does not form a proper basis for rejection.

Regarding the remaining references, the Examiner again contends that the '323 patent teaches a translocation portion. Again, Applicants respectfully point out that the '323 patent does not teach a translocation portion nor does it disclose any motivation to include a translocation domain. There is no reference to translocation or internal cell targeting of any nature nor anything to suggest that inclusion of a translocation portion would be beneficial. Thus, there is no

motivation to replace the anti-immunoglobulin antibody that binds to B-cell surface immunoglobulins with any other binding portion. In addition, the Examiner contends that Fawell et al teaches the use of the HIV tat protein for cellular translocation and that Noguchi et al teaches the use of p53 as a candidate for T cell recognition.

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive to support the combination. The combined disclosures of the '323 patent, Fawell et al, and Noguchi et al do not teach or suggest Applicant's combination of elements.

Therefore, the rejection of rejected Claims 1, 2, 4 and 13 under 35 U.S.C. § 103(a) as obvious is improper and accordingly, Applicants respectfully request that the rejection of Claims 1 to 3 and 5 to 23 under 35 U.S.C. § 103(a) be withdrawn.

In view of the above amendments and Applicants' remarks, the claims are believed to be in condition for allowance. Reconsideration, withdrawal of the rejections, and passage of the case to issue is respectfully requested.

If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-1265. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

NIKOLAI, MERSEREAU & DIETZ, P.A.

Date:_____

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